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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,777	07/07/2006	Michael J. Yaszemski	630666.00008	4282
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EXAMINER				
LSTVOYB, GREGORY				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/562,777

Applicant(s)

YASZEMSKI ET AL.

Examiner

GREGORY LISTVOYB

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7, 9 and 14-17 is/are pending in the application.
4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 2-7 and 9 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 rejected under 35 U.S.C. 102(b) as being anticipated by Wiggins ("Design of bioabsorbable, amorphous polymer networks and composites" Thesis, Univ of S. Mississippi, 1992) herein Wiggins.

Wiggins discloses a copolymer comprising: caprolactone units and fumarate units (i.e. L-lactide-co-caprolactone fumarate, Abstract, p.2).

The transitional phrase "consisting essentially of" is noted.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

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"It is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language." *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Claims 2 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al ("Syntheses and evaluation of biodegradable multifunctional polymer networks", Eur. Polym Journal, 39, 1817-1822) herein Chung.

Chung discloses a copolymer, containing PCL and fumarate moieties (p.1820 see PCL900/TMA/DPFDMA structure).

Regarding Claim 9, PCL 900 (polycaprolactone, having molecular weight in range of 500-10000 daltons) and fumaryl chloride participate in preparation of the above structure.

The transitional phrase "consisting essentially of" is noted.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

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"It is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language." *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Claim 2 rejected under 35 U.S.C. 102(b) as being anticipated by Fisk et al (US patent 4082816) herein Fisk.

Fisk discloses a copolymer comprising caprolactone units and fumarate units, which obtained by polymerization of caprolactone and fumaric acid (Column 1, line 15 and Column 2, line 10).

Fisk does not disclose the above synthesis in his Examples. However, in this rejection Examiner relies on the full disclosure of the Fisk's patent.

Claims 2-7 rejected under 35 U.S.C. 102(b) as being anticipated by Breant et al (US patent 5747605) herein Breant.

Breant discloses a copolymer obtained from fumaric acid (Column 2, line 5) and polycaprolactone (PCL). Breant teaches that melting point of the product is 60C, where the copolymer injectable above melting point (column 2, line 65).

In reference to Claim 3 and 4, since melting point of Breant's copolymer is in the same range, as one of a copolymer of the application examined and the polymers

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above have similar structures, Breant's polymer inherently has molecular weight characteristics, similar to one of the Application.

Note that Breant uses two types of initial caprolactam oligomer. One of them is defined as polycaprolactam having Molecular Mass of 80000 and Melt Index (MI) of 4.5 dg/min. Another one has much higher MI of 30 dg/min, which corresponds with MW, which is much lower than 80000.

Regarding claim 7, since Breant 's PCL-fumarate has similar structure as the one in the Application, it is the Examiner's position that hardening point of Breant's copolymer is within 30-40C.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim9 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Breant.

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Claim 9 represents product-by-process Claim. Since Breant's and Application's polymers are identical, the process of claim 9 does not convey any patentable distinct features to the product.(see MPEP 2113).

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process" *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See Also *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974), *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over Kweon et al ("A novel degradable polycaprolactone networks for tissue engineering", *Biomaterials* 24(2003), 801-808), herein Kweon in combination with Chung.

Kweon discloses a novel degradable polylactone network for tissue engineering. In order to obtain the above structure, he uses PLC macromer with $M_n=1250$ and 2000 and chloride of ethylenically unsaturated acid.

Kweon does not teach a fumaril chloride as a starting component.

Chung discloses a reaction of fumaryl chloride with diglycol and PCL with methacryloyl chloride to produce an injectable, biodegradable interpenetrating network (Abstract, Fig 1 and Fig 2 and page 1820). Chung teaches that addition of the fumaric acid fragments allows the formulation of biodegradable polymer with good strength, viscosity and low polymerization shrinkage.

Therefore, it would have been obvious to a person of ordinary skills in the art to use fumaril chloride in Kweon's polymers to achieve the above properties in order to obtain biodegradable polymer with good strength, viscosity and low polymerization shrinkage.

Response to Arguments

Applicant's arguments filed 9/20/2007 have been fully considered but they are not persuasive.

Regarding Chung, Fisk and Kweon references the applicant states that methacrylate groups of Chung may adversely affect the biodegradability of a polymer. The Applicant should present relevant data to prove this statement. The Applicant relies on page 2, line 29 of the present specification there polymethylmethacrylate is mentioned. In contrast, only small methacrylic fragments present in Chung's and Fisk's polymers.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

"It is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language." *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Applicant argues that Chung does not teach a self-crosslinkable copolymer as claimed in claim 2 of the present invention.

First, clause "self-crosslinkable" does not mean self-crosslinked. Even saturated olefins can be self-cross-linked under appropriate treatment. Second, in the Specification the Applicant states that his copolymer contains a fumaric acid, which contains

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unsaturated carbon-carbon double bonds that can be used for in situ crosslinking (see line 25). Chung's polymer contains fumarate moieties.

The same arguments are relevant to Fisks, Kweon and Breant's references.

In reference to Breant's reference the Applicant states that "Breant has prepared polymers in which the "polycaprolactones employed are of high molecular weights and of two types: Tone 767E supplied by Union Carbide Company, of melt index of 30 dg/min, measured at 190.degree. C. under a 2.16-kg load. Capa 680, supplied by Solvay Interlox, of molecular mass of 80,000".

As discussed above, Breant uses two types of initial caprolactam polymer. One of them is defined as polycaprolactam having Molecular Mass of 80000 and Melt Index (MI) of 4.5 dg/min. Another one has much higher MI of 30 dg/min, which corresponds with MW, which is much lower than 80000. Additionally, since melting point of Breant's copolymer is in the same range, as one of a copolymer of the application examined and the polymers above have similar structures, Breant's polymer inherently has molecular weight characteristics, similar to one of the Application. (see discussion above).

Applicant argues that Tone 767E (used by Breant) poly caprolactone has a molecular mass of 43,000 (based on Peluso et al., Journal of Biomedical Materials Research, Part A, Volume 34, Issue 3, Pages 327 - 336).

However, Peluso article is not presented to Examiner attention. In addition, molecular weight in Peluso is not defined (i.e it is not clear from Applicant's remarks whether Peluso refers to M_z, M_w or M_n).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rabon Sergent/
Primary Examiner, Art Unit 1796

GL